IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., CITY OF HOPE, and HOFFMANN-LA ROCHE INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 18-1025 (CFC)
CELLTRION, INC., CELLTRION HEALTHCARE, CO. LTD., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS INTERNATIONAL GMBH,	)	
Defendants.	)	

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS DEFENDANTS' COUNTERCLAIMS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES, RULES & REGULATIONS

I. INTRODUCTION

Nine months ago, Celltrion abandoned the patent dance and filed suit in its favored forum, California. But that strategic decision came with a price: by failing to complete the patent dance as required by the BPCIA, Celltrion forfeited the right to bring declaratory-judgment claims, including the declaratory-judgment counterclaims that it has asserted here.

To avoid the consequence of its deliberate choice to abandon the patent dance, Celltrion makes arguments that are contrary to the BPCIA's text and policy goals. First, Celltrion argues that the BPCIA's declaratory-judgment bar does not apply to counterclaims, but this runs counter to the plain language of the statute and would lead to outcomes that frustrate its objectives. Second, Celltrion argues that the BPCIA allows a biosimilar applicant to indefinitely pause the patent dance. But this argument also finds no support in the BPCIA's text, and it would result in a system that is the opposite of the orderly and expeditious process that Congress intended.

The BPCIA gives biosimilar applicants like Celltrion a choice: either comply with the patent dance's case-narrowing exchanges and be able to exercise substantial control over the scope of the resulting litigation or refuse to comply with the patent dance and forfeit the right to control the litigation's scope. Celltrion chose the latter. As a result, Celltrion may only pursue its non-infringement and invalidity arguments as affirmative defenses; it cannot dictate the scope of this case by raising those arguments as declaratory-judgment counterclaims. This may create some uncertainty for Celltrion, but Celltrion brought that uncertainty upon itself by knowingly giving up its statutory place in the driver's seat to pursue other strategic goals. To preserve the integrity of the BPCIA's "carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement," *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017), Celltrion's counterclaims should be dismissed in their entirety.

II. ARGUMENT

A. Section 262(*l*)(9)(B)'s declaratory-judgment bar applies to counterclaims.

Celltrion devotes the bulk of its brief to a novel statutory argument: that bringing a counterclaim is different from "bring[ing] an action," as that phrase is used in the BPCIA's declaratory-judgment bar, 42 U.S.C. § 262(*l*)(9)(B). Celltrion's reading of the statute is contrary to both its plain language and its policy goals.

1. *The plain language of § 262(l)(9)(B) bars Celltrion's counterclaims.*

Section 262(*l*)(9)(B) provides that "[i]f a subsection (k) applicant fails to complete an action required [under any of five subsections of the BPCIA], the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28." 42 U.S.C. § 262(*l*)(9)(B). The structure of the statute is straightforward: if a biosimilar applicant, like Celltrion, fails to complete certain actions, then it is barred from "bring[ing] an action" for a declaratory judgment.

Celltrion does not dispute this basic structure, nor does it dispute that a counterclaim is an "action" as that term is generally understood. Instead, it focuses its argument on the word "bring," suggesting that this word somehow limits an "action" to the filing of a complaint. But there is nothing inherent in the word "bring" that excludes counterclaims. *Cf. Indus. Eng'g & Dev., Inc. v. Static Control Components, Inc.*, 45 F. Supp. 3d 1311, 1320 (M.D. Fla. 2014) (holding that a term in a patent-license agreement saying that a licensee may not "file an action" challenging the validity of the patent prohibited the licensee from filing a counterclaim challenging the validity of the patent because "a reasonable interpretation of 'file an action' is 'file an independent cause of action seeking affirmative relief'"). Celltrion concedes that courts routinely refer to parties "bringing a counterclaim," as even the Supreme Court has recently done in a patent case. *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 413

(2012) ("An ANDA applicant sued for patent infringement may ***bring a counterclaim*** on the ground that the patent does not claim an approved method of using the drug.") (internal quotation marks omitted, emphasis added). Although Celltrion contends that this usage—which directly undercuts its strained reading of the BPCIA—is "irrelevant," Opp. at 11, it provides no explanation for why the word "bring" somehow narrows the scope of "action" in § 262(*l*)(9)(B).

Instead of analyzing the plain meaning of the BPCIA's text, Celltrion relies heavily on the Third Circuit's *Jonathan H.* decision, which interpreted the phrase "bring an action" in an entirely different statutory scheme—the Individuals with Disabilities Education Improvement Act of 2004, 20 U.S.C. § 1415 ("IDEA"). *See Jonathan H. v. Souderton Area School Dist.*, 562 F.3d 527, 529-30 (3d Cir. 2009); *see also Ruben A. v. El Paso Indep. Sch. Dist.*, 414 F. App'x 704, 707 (5th Cir. 2011) (adopting *Jonathan H.*'s holding, without further analysis, in another IDEA case). But key differences between the IDEA and the BPCIA demonstrate that *Jonathan H.*'s reasoning should not be extended to this case.[1]

The IDEA allows a student to seek certain accommodations from a public school before an administrative hearing officer. *Jonathan H.*, 562 F.3d at 528. If the student or the school is dissatisfied with the hearing officer's decision, it may "bring a civil action" seeking judicial review. 20 U.S.C. § 1415(i)(2)(A). "The party bringing the action shall have 90 days from the

[1] Celltrion also cites two cases suggesting that a party "bring[s] an action" by initiating it. These cases, however, are about the ***timing*** of when an action is deemed brought, not about whether counterclaims constitute "bring[ing] an action," which is the issue in this case. In *Chandler v. D.C. Department of Corrections*, 145 F.3d 1355, 1358 (D.C. Cir. 1998), Congress enacted a cap on the number of times a prisoner could "bring a civil action or appeal a judgment" *in forma pauperis* while the appeal was pending. *Id.* at 1357-58. The appeal would have been barred if the cap applied, but the court held that it did not because "bring a civil action or appeal a judgment" referred to the act of initiating a suit or an appeal, not prosecuting one that had already been initiated. *Id.* at 1358. Likewise, *Beeler-Lopez v. Dodeka, LLC*, 711 F. Supp. 2d 679, 681 (E.D. Tex. 2010), held that a debt collector's new counsel was not liable under the Fair Debt Collection Practices Act for taking over an improperly venued action because the new counsel did not "bring" (i.e., initiate) the action. Neither decision considered counterclaims.

date of the decision of the hearing officer to bring such an action." *Id.* § 1415(i)(2)(B).

In *Jonathan H.*, neither the student nor the school was satisfied with the hearing officer's decision. *See* 562 F.3d at 528. The student filed a civil action challenging it on the last day of the limitations period, and the school filed counterclaims challenging the decision with its answer several weeks later. *Id.* The case was formally a civil action presenting cross-motions for summary judgment, but it was functionally the same as a cross-appeal.

The district court deemed the school's counterclaims untimely because they were brought after the 90-day limitations period expired, *id.*, but the Third Circuit reversed. The Third Circuit concluded that "a defendant does not 'bring an action' by asserting a counterclaim; only a plaintiff may 'bring an action' ***for purposes of the IDEA***." *Id.* at 530 (emphasis added). Policy concerns were pervasive in the Third Circuit's decision. The court explained, for example, that its interpretation resulted in the "fairer rule," since it prevented a scenario in which a party could lose its right to effectively cross-appeal a mixed judgment because of its adversary's gamesmanship. *Id.* It also noted that its interpretation prevented "unnecessary litigation" by eliminating the need for all parties to "file 'protective complaints' to preserve issues adjudicated against them, even when they otherwise would countenance the administrative judgment." *Id.*

Genentech is unaware of any court extending *Jonathan H.*'s reasoning beyond the IDEA, and Celltrion cites none. And the policy concerns underlying *Jonathan H.* not only do not apply here, but are contrary to those of the BPCIA (discussed below). A biosimilar applicant like Celltrion only becomes subject to the BPCIA's declaratory-judgment bar if it "fails to complete an action required of [it] under" the patent dance. 42 U.S.C. § 262(*l*)(9)(B). There is no scenario in which a reference-product sponsor's gamesmanship can cause the biosimilar applicant to lose its right to pursue declaratory-judgment claims—only the biosimilar applicant's actions, like

Celltrion's decision to intentionally forgo the patent dance and sue Genentech in California, can do that.

Apparently recognizing the weaknesses of relying solely on *Jonathan H.*, Celltrion's opposition brief suggests that the Northern District of California has already settled the question of whether § 262(*l*)(9)(B) bars declaratory-judgment counterclaims. *See* Opp. at 9 (discussing *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-4741-RS, 2015 WL 1264756, at *9 (N.D. Cal. Mar. 19, 2015)). Not so. The issue in *Amgen* was whether a biosimilar applicant is required to comply ***at all*** with the BPCIA's information exchanges, not what the consequences are of a biosimilar applicant abandoning the patent dance after beginning it. *Amgen*, 2015 WL 1264756, at *5-6. To the extent the district court in *Amgen* addressed the consequences of a biosimilar applicant's failure to participate at all in the patent dance on the biosimilar applicant's ability to bring declaratory-judgment counterclaims, the court did so only in passing, with little briefing, and in a context of a different statutory subsection—i.e., § 262(*l*)(9)(C). That aspect of *Amgen* has never been reviewed on appeal,[2] and it does not negate the Northern District of California's decision against Celltrion that the very declaratory-judgment claims that Celltrion is seeking to assert here are barred under § 262(*l*)(9)(B). *See Celltrion, Inc. v. Genentech, Inc.*, No. 18-cv-00274-JSW, 2018 WL 2448254, at *5 (N.D. Cal. May 9, 2018).

Nor is there anything about the district court's analysis in *Amgen* that would favor extending its reasoning here. After four lines of analysis, the court allowed Sandoz to maintain its counterclaim notwithstanding § 262(*l*)(9)(C). *Amgen* cited only two cases, neither of which directly considered the proper construction of "bring an action," to support this decision: a 1935

[2] The California court entered final judgment on the patent-dance-related issues after deciding the cross-motions for judgment on the pleadings, launching the appeal that ended up at the Supreme Court. The district court did not enter judgment or certify an interlocutory appeal on the counterclaim issue, so the appeals did not address it. *See Amgen*, 2015 WL 13688445, at *1-2.

Supreme Court case holding that the venue provision in the Judicial Code of 1911 did not apply to counterclaims brought against claimants in a receivership, *Alexander v. Hillman*, 296 U.S. 222, 240-41 (1935), and a decision holding that a judicially created doctrine barring certain counterclaims against a False Claims Act relator does not bar all counterclaims, *U.S. ex rel. Miller v. Bill Harbert Int'l Const., Inc.*, 505 F. Supp. 2d 20, 26-27 (D.D.C. 2007). Neither the court nor the parties' briefs considered any of the authority cited in Genentech's motion (D.I. 16 at 15-19); other uses of "action" in the Patent Act (as in 35 U.S.C. § 315(a)(1), discussed at D.I. 16 at 16-17); the BPCIA's structure or policy goals (*id.* at 18-19); or the effect of excluding counterclaims from the scope of "action" on other parts of the BPCIA (discussed in the next section). In short, *Amgen*'s limited analysis of a different statutory subsection on different facts does not support Celltrion's arguments about the proper application of § 262(*l*)(9)(B) in this case.

2. *Celltrion's narrow reading of § 262(l)(9)(B) is inconsistent with the BPCIA's goals.*

Celltrion's policy argument for excluding counterclaims from § 262(*l*)(9)(B) fares no better than its textual arguments. Celltrion contends that any interpretation of § 262(*l*)(9)(B) that denies it "certainty . . . for the commercial launch of biosimilar products" is contrary to Congress's intent. Opp. at 12. But the BPCIA only grants a biosimilar applicant "certainty" when it complies with the patent dance, which Celltrion did not do here. *Cf. Sandoz*, 137 S. Ct. at 1672 (noting "various consequences for failing" to comply with the patent dance). And Celltrion also presents a one-sided picture of the BPCIA's goals, which include resolving disputes "expeditiously" and "providing certainty to . . . the reference product manufacturer[] and the public at large." *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1063 (Fed. Cir. 2016) (omitted parts of legislative history that Celltrion quotes at Opp. 12). As Genentech's opening brief explains, there must be meaningful penalties to ensure that a biosimilar applicant complies

with the patent dance, D.I. 16 at 9-10, which is the "carefully calibrated scheme" that Congress created to balance the statute's competing goals, *Sandoz*, 137 S. Ct. at 1670. There is nothing inequitable about penalizing a party like Celltrion—which abandoned the patent dance and filed a statutorily barred complaint—for upsetting this balance to further its own strategic ends.

And if "certainty" is what Celltrion wants, its proposed interpretation of the BPCIA is not the way to get it. To ensure that a biosimilar applicant is on notice of the patents its product might infringe, the BPCIA requires the reference-product sponsor (i.e., Genentech) to provide the applicant with a list of all such patents (i.e., a 3A List). *See* 42 U.S.C. § 262(*l*)(3)(A). If the sponsor fails to include a patent on its 3A List, it cannot sue the applicant for infringing the patent. The BPCIA provides that "the owner of a patent that should have been included in the [3A] list [or supplement] for a biological product, but was not timely included in such list, ***may not bring an action*** under this section for infringement of the patent with respect to the biological product." 35 U.S.C. § 271(e)(6)(C) (emphasis added).

It is a "normal rule of statutory interpretation that identical words used in different parts of the same statute are generally presumed to have the same meaning." *IBP, Inc. v. Alvarez*, 546 U.S. 21, 34 (2005). If Celltrion is right that "bring an action" in § 262(*l*)(9)(B) excludes counterclaims, then "bring an action" in § 271(e)(6)(C) does too. This would allow Genentech to assert any patent in its portfolio against Celltrion as a counterclaim in any case in which Celltrion is a plaintiff (e.g., in its California case, if it is revived on appeal, or in a second-phase BPCIA case). This outcome—which would render the narrowing functions of the patent dance meaningless—would create far more uncertainty for Celltrion than dismissing its counterclaims would. Celltrion will almost certainly disagree with this reading of § 271(e)(6)(C), but there is no way to reconcile that disagreement with Celltrion's interpretation of § 262(*l*)(9)(B).

The plain meaning of "bring an action" encompasses bringing counterclaims. Nothing in the BPCIA supports deviating from that plain meaning, and the policy underlying the statute provides ample reason for refusing to do so. Celltrion's strained statutory-interpretation argument should therefore be rejected.

B. Celltrion's counterclaims are barred by § 262(*l*)(9)(B).

Celltrion next tries to salvage its counterclaims by arguing that it discharged its statutory duties either before it filed its California complaint or when it served its untimely "5A Number" in June. Neither argument bears scrutiny. Because Celltrion failed to complete its obligations under § 262(*l*)(9)(B), its counterclaims should be dismissed.

First, Celltrion's attempt to rehash whether it had complied with § 262(*l*)(5) when it filed its California complaint is both procedurally improper and without merit. Celltrion concedes, as it must, that the California court dismissed its complaint because "Celltrion failed to complete its obligations under section 262(*l*)(5) by the time it filed suit in California." Opp. at 13. Final judgment has entered in that case, D.I. 17, Ex. 6, so Celltrion is collaterally estopped from relitigating the issue here.[3]

Second, as explained in Genentech's opening brief (D.I. 16 at 13-14), Celltrion's recent actions cannot resurrect the patent dance that it abandoned in January. Celltrion makes no serious attempt to dispute this; instead, it wholeheartedly embraces a reading of the BPCIA that would allow a biosimilar applicant to unilaterally and indefinitely delay the patent dance and resurrect it on a whim. Celltrion agrees that "[§ 262(*l*)(4)(B)] gives the parties 15 days to

[3] *See, e.g.*, *United Access Techs., LLC v. CenturyTel Broadband Servs. LLC*, 778 F.3d 1327, 1331 (Fed. Cir. 2015) (listing collateral estoppel elements, which are met here); *Galderma Labs. Inc. v. Amneal Pharm., LLC*, 921 F. Supp. 2d 278, 281 (D. Del. 2012) (finality not affected by appeal). Even if the Court were to consider these arguments, the California court's thorough opinion provides a roadmap for rejecting them. *See Celltrion, Inc. v. Genentech, Inc.*, No. 18-CV-00274-JSW, 2018 WL 2448254, at *5-8 (N.D. Cal. May 9, 2018).

negotiate and agree on a list of patents that will be the subject of a first round of litigation," but it contends that "nothing in [§ 262(*l*)(5)] suggests the biosimilar applicant must provide its (5)(A) designation on the very first day after the time to negotiate has expired." Opp. at 14. In other words, Celltrion argues that if the parties fail to reach agreement within the 15-day period of § 262(*l*)(4)(B), then the biosimilar applicant may indefinitely suspend the patent dance and unilaterally resume it at the applicant's convenience. The more logical reading of the statute—and certainly the one that is more consistent with the BPCIA's aim of a "streamlined patent resolution process . . . [that] will help ensure that litigation surrounding relevant patents will be resolved expeditiously," *Amgen*, 827 F.3d at 1063 (quoting BPCIA's legislative history)—is that the biosimilar applicant must comply with its obligations under § 262(*l*)(5)(A) immediately upon expiration of the 15-day period in § 262(*l*)(4)(B). There is nothing streamlined or expeditious about a process that lets one party unilaterally and indefinitely delay it.[4]

Celltrion's attempt to characterize this case as "premised upon" its completion of the patent dance is meritless. As Genentech explained in both its complaint and in a letter to the Court in the 18-095 case, Genentech filed this complaint to protect its rights against Celltrion's gamesmanship. *See* D.I. 1, ¶ 14; Ltr. from M. Noreika Regarding Related Case, C.A. 18-095, D.I. 39. Celltrion has made a habit of starting and stopping the patent-dance process to further its strategic goals. In another BPCIA case in Massachusetts (involving a non-Genentech drug), Celltrion abandoned the patent dance for almost two years, litigated two cases through the close of fact discovery, and then sought to reopen the patent-dance negotiations. *See* D.I. 17, Ex. 9, ¶ 11. The reference-product sponsor objected, as Genentech did here, but Celltrion threatened to

[4] Celltrion asserts that it complied with other requirements under the BPCIA after filing its counterclaims in this case, such as the requirement to notify the Secretary of Health & Human Services of Genentech's complaint under § 262(*l*)(6)(C)(i). Opp. at 16. However, Celltrion's purported compliance with § 262(*l*)(6)(C)(i) does not cure its failure to satisfy other statutory prerequisites to seeking declaratory relief, including § 262(*l*)(5)(A).

invoke the BPCIA's limitations on the patent holder's remedies—a sanction built into the BPCIA for a reference-product sponsor that fails to complete the patent dance, 35 U.S.C. § 271(e)(6)(B)—if the reference-product sponsor did not sue it again. *Id.* To avoid that draconian penalty, and to avoid burdening the court with motion practice about it, the plaintiff in the Massachusetts case filed such a complaint. *Id.* ¶ 12. Celltrion tried the same thing here (and in a case involving another Genentech drug in New Jersey), and Genentech responded the same way. This suit is not premised upon Celltrion's completion of the patent dance—it is premised upon Genentech's desire to avoid further procedural games.

III. CONCLUSION

Because Celltrion failed to complete the patent dance, its counterclaims are barred by § 262(*l*)(9)(B). Celltrion's counterclaims should therefore be dismissed in their entirety.

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September 28, 2018

CERTIFICATE OF SERVICE

I hereby certify that on September 28, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 28, 2018, upon the following at the email addresses indicated below:

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